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09/993,180	11/14/2001	Jian Chen	D0051 NP	2612

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EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
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1652

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DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/993,180

Applicant(s)

CHEN ET AL.

Examiner

William W. Moore

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- 5      1. Claims 1, 5, 7-10, 14, 15 and 44, drawn in part, and claims 2-4, 45, 46, 48 and 49 drawn entirely, to a polynucleotide fragment having at least 95% identity to polynucleotide having the sequence of SEQ ID NO:1 and encoding a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having native serpin inhibitory activity, to vectors comprising the polynucleotide fragment, to host cells comprising the polynucleotide fragment and a method of making a host cell comprising the polynucleotide fragment, and to a recombinant method of making of an encoded serpin in a host cell using the polynucleotide, classified, *inter alia*, in class 435, subclass 69.2.
- 10      2. Claim 21, drawn to a polynucleotide which is a gene that provides, upon transcription a "cDNA sequence of SEQ ID NO:2", classified in class 536, subclass 23.5.
- 15      3. Claims 1, 5, 7-10, 14, 15 and 44 drawn, in part, and claims 5, 6, and 47 drawn entirely, to a polynucleotide fragment having at least 95% identity to polynucleotide having a region of the sequence of SEQ ID NO:1 sufficient to encode a polypeptide domain or epitope present in SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, e.g., any of SEQ IDs NOs:21-23, to vectors comprising the polynucleotide fragment, to host cells comprising the polynucleotide fragment and a method of making a host cell comprising the polynucleotide fragment, and to a recombinant method of making of an encoded polypeptide domain or epitope in a host cell using the polynucleotide, classified, *inter alia*, in class 435, subclass 69.3.
- 20      4. Claims 11, 16, 20, and 50, drawn, in part, to a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having native serpin inhibitory activity, and to a method for identifying a binding partner affecting the activity of the polypeptide, classified in class 530, subclass 350.
- 25      5. Claims 11, 12, 16, and 20, a polypeptide comprising polypeptide domain or epitope present in SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, e.g., any of SEQ IDs NOs:21-23, and to a method for identifying a binding partner capable of affecting the activity of the polypeptide domain or epitope, classified in class 530, subclass 300.
- 30      6. Claim 13, drawn, in part, to an antibody capable of specifically binding to a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having the inhibitory activity of the native serpin, classified in class 530, subclass 387.9.
- 35      7. Claim 13, drawn, in part, to an antibody capable of specifically binding to a domain or epitope of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, classified in class 530, subclass 387.1.
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Art Unit: 1652

- 5 8. Claims 17, 26-30 and 40-43, all drawn in part to a method for preventing, treating or ameliorating various medical conditions comprising a therapeutic administration to a subject of a composition comprising a polynucleotide fragment having at least 95% identity to polynucleotide having the sequence of SEQ ID NO:1 and encoding a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having the inhibitory activity of the native serpin, classified in class 514, subclass 44.
- 10 9. Claim 17, 26-30, and 40-43, all drawn in part to a method for preventing, treating or ameliorating various medical conditions comprising a therapeutic administration to a subject of a composition comprising polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having the inhibitory activity of the native serpin, classified in class 514, subclass 2.
- 15 10. Claim 18, drawn to a diagnostic assay comprising determining the presence or amount of expression in a biological sample of a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, classified in class 435, subclass 6.
- 20 11. Claim 19, drawn to a diagnostic assay comprising determining the presence or absence in a biological sample of a mutation in a polynucleotide fragment having at least 95% identity to polynucleotide having the sequence of SEQ ID NO:1 and encoding a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, classified in class 435, subclass 7.71.
- 25 12. Claim 22, drawn to a method of identifying an unspecified activity in a biological assay comprising expression of a polynucleotide having the sequence of SEQ ID NO:1 in a cell, classified in class 435, subclass 69.1.
- 30 13. Claim 23, drawn to an unspecified product somehow produced by a method for identifying a binding partner capable of affecting the activity of a polypeptide comprising a mature serpin of SEQ ID NO:2 or the polypeptide encoded by the cDNA sequence present in the ATCC deposit No. PTA-2766, or variants thereof having native serpin inhibitory activity, classified in class 514, subclass 1.
- 35 14. Claim 24, drawn to a process for variegating a polynucleotide sequence encoding a serpin and selecting sequences encoding functional products upon expression of the variegated polynucleotide, classified in class 435, subclass 471.
- 40 15. Claim 25, drawn to a variegated polynucleotide encoding an altered polypeptide, classified in class 536, subclass 23.1.
16. Claims 31, 32, and 36-39 drawn to a computer and methods for identifying structures therewith, classified in class 709, subclass 1.
17. Claims 33-34, drawn to a molecular serpin model and methods for designing mutant molecules therewith, classified in class 434, subclass 278.
18. Claim 35, drawn to a method for identifying modulatory molecules using a serpin molecular model, classified in class 73, subclass 866.

Art Unit: 1652

19. Claims 51 and 52, drawn to an assay method for identifying a compound capable of modulating the activity of a potassium channel  $\beta$  subunit, classified in class 435, subclass 7.2.

The inventions are distinct, each from the other, because of the following reasons:

5       Inventions of Groups 2 and 1 are related, respectively, as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does  
10       not require the particulars of the subcombination as claimed because a combination of claim 21 requires none of the variations embraced by clauses (a)-(c) and (e)-(l) of claim 1 and because the subcombinations of claim 1 have separate utility in an other combination, such as an expression vector.

      Inventions of Groups 1 and 3 are related as combination and subcombination.  
15       Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the  
20       particulars of the subcombination as claimed because the combination of clauses (a)-(c) and (e)-(l) of claim 1 encodes an integral serpin polypeptide having a physiological activity and because the subcombinations of clause (d) of 1 and claims 5, 6, and 47 have separate utility in an other combination, encoding a peptide for conjugation to a carrier protein used to elicit a monospecific immune response.

      Inventions of Groups 1 and 4 are related as process of making and product made.  
25       The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

30       Inventions of Group 1 and Groups 8 and 11 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

Art Unit: 1652

different process of using that product (MPEP §806.05(h)). In the instant case the product as claimed can be used in a materially different process, that of recombinant production in a transformed host cell of an encoded serpin polypeptide.

5 The invention of Group 1 is unrelated to the inventions of Groups 5-7, 9, 10, and 12-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

10 The invention of Group 2 is unrelated to the inventions of Groups 3-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

15 Inventions of Groups 3 and 5 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §  
20 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

25 Inventions of Groups 3 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the product as claimed can be used in a materially different process, that of recombinant production in a transformed host cell of a polypeptide exhibiting a serpin epitope or domain.

30 The invention of Group 3 is unrelated to the inventions of Groups 4, 6-10, and 12-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the

Art Unit: 1652

different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 4 and 5 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of clauses (a), (b), and (e)-(l) of claim 11 is an integral serpin polypeptide having a physiological activity and because the subcombinations of clauses (c) and (d) of claim 11 have separate utility by themselves as peptides for conjugation to a carrier protein used to elicit a monospecific immune response.

Inventions of Group 4 and Groups 9 and 10 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the product as claimed can be used in a materially different process, that of identifying a binding partner of a serpin.

The invention of Group 4 is unrelated to the inventions of Groups 6-8 and 11-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

The invention of Group 5 is unrelated to the inventions of Groups 6-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

Art Unit: 1652

Inventions of Groups 6 and 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have either different functions or different effects.

The invention of Group 6 is unrelated to the inventions of Groups 8-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

The invention of Group 7 is unrelated to the inventions of Groups 8-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and different effects.

The invention of Group 8 is unrelated to the inventions of Groups 9-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

The invention of Group 9 is unrelated to the inventions of Groups 10-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

The invention of Group 10 is unrelated to the inventions of Groups 11-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or



Art Unit: 1652

they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

5 The invention of Group 11 is unrelated to the inventions of Groups 12-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

10 The invention of Group 12 is unrelated to the inventions of Groups 13-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

15 The invention of Group 13 is unrelated to the inventions of Groups 14-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

20 The invention of Group 14 is unrelated to the inventions of Groups 15-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

25 The invention of Group 15 is unrelated to the inventions of Groups 16-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the

Art Unit: 1652

different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

5 The invention of Group 16 is unrelated to the inventions of Groups 17-19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

10 Inventions of Groups 17 and 18 are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the product as claimed can be used in a materially different process, that of designing mutant serpins.

15 The invention of Group 17 is unrelated to the inventions of Groups 18 and 19. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

20 Inventions of Groups 18 and 19 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP §806.04, MPEP §808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation, different functions, and have different effects.

25 Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification restriction for examination purposes as indicated is proper.

30 Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(h).

Art Unit: 1652

A telephone call was made to Mr. Stephen D'Amico on July 1, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made.

*Conclusion*

5 Any inquiry concerning this communication or earlier communications from the  
examiner should be directed to William W. Moore whose telephone number is  
703.308.0583. The examiner can normally be reached from 8:00AM-6:30PM EST on  
10 Mondays, Wednesdays, and Fridays and from 11:30AM-6:00PM EST on Tuesdays and  
Thursdays. If attempts to reach the examiner by telephone are unsuccessful, the  
examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804.  
The fax phone numbers for the organization where this application or proceeding is  
15 assigned are 703.308.4242 for regular communications and 703.308.0294 for After  
Final communications. Any inquiry of a general nature or relating to the status of this  
application or proceeding should be directed to the receptionist whose telephone number  
is 703.308.0196.



William W. Moore  
June 30, 2003